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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,447	11/17/2003	Edward Roberts	7567/80871	9363

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ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

KL

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/714,447	ROBERTS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Emily Bernhardt	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/15/05 (RCE Request).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

S.O.D

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/05 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 19 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Calderon and Bilsky references in view of Chang (WO'062 or US'908, applied as of its 102(e) date) for reasons set forth in the action mailed 3/22/05.

In the RCE request applicants continue to rely on their remarks made in the after final response. However, the traverse to the rejection remains not persuasive for the following reasons. It is not agreed that the passage in Chang (col.6) requires one of R3-R5 to be Me. What it does say is that no more than 2 R groups can be Me. This is consistent with the claims which include a proviso forcing one of R3-R5 to be Me. If applicants' interpretation was correct, then the proviso would not be needed in claim 1 since the same language otherwise appears there that appears in col.6. The proviso was apparently added to exclude any H's on these R groups

to avoid prior art. The fact that Chang's compounds have the amide group on the *meta* position of the phenyl ring vs. instant *para* does not lessen the validity of the rejection since Chang was applied as a secondary reference and as such is expected to have some differences over the claimed invention for it otherwise would be a primary reference or an anticipation. Chang is drawn to very similar compounds from the same art area. Additionally, Chang's invention also includes *para* isomers as set forth in col.20. Applicants' final remarks that instant compounds are selective delta agonists are also not convincing since the compounds of the primary reference are also described to have this selectivity for treating the same uses as herein and as in Chang. The thrust of Chang's invention is to develop highly selective opioid agonists as discussed in cols. 17-18 and in the background section and this includes selective delta agonists. See col.20. Thus in the absence of any superior and unexpected results, the closest instant compounds to those in the primary reference are presumed to be also selective delta agonists and thus a patentable distinction is not seen.

The following rejection is being reinstated.

Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,696,447. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the subject matter covered by the claims in the US patent (which has a later effective filing date) has species that anticipate the instant claims. In applicants' response of 12/30/04 this rejection was traversed on the grounds that the subject matter covered by the claims of the US patent was deemed patentably distinct and could not otherwise have been filed in the earlier case, namely the instant case. A review of the MPEP 804, section (a), p.88-23, August 2001 Ed. states that **where an application at issue is the earlier filed application, only a one-way determination** (for obviousness) is required **unless two conditions** are met. In the instant case prong A ,i.e. sufficient evidence of administrative delay on the part of the PTO, has not been met and thus the rejection must be made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number: 10/714,447  
Art Unit: 1624

Page 5

*E Bernhardt*  
Emily Bernhardt  
Primary Examiner  
Art Unit 1624